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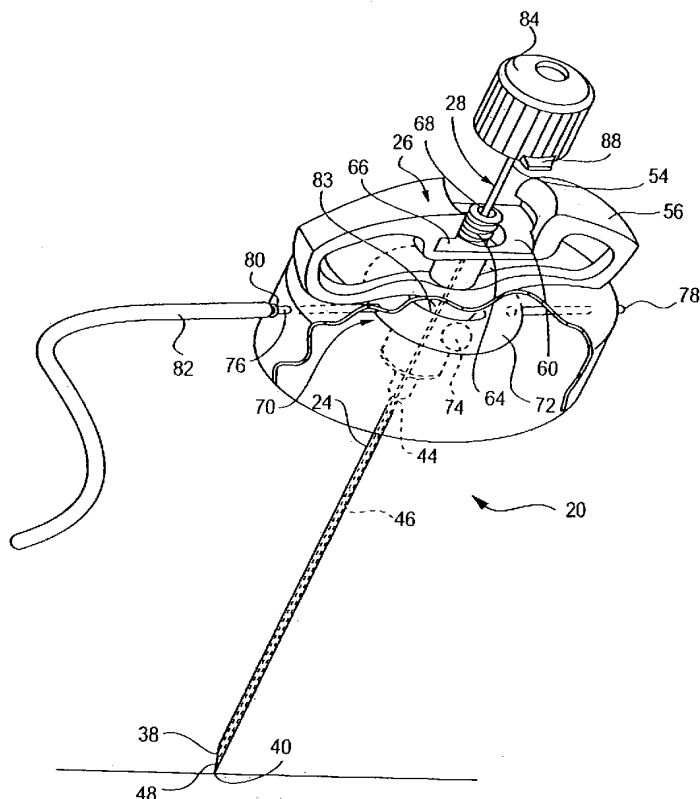
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(54) Title: CEMENT DELIVERY NEEDLE



(57) Abstract: A cement delivery needle apparatus (20) and a method of flowing a bone cement through a vertebroplasty needle apparatus are provided. The cement delivery needle apparatus (20) includes a sheath (24) and a handle (26). The sheath (24) has an inlet (44) to receive a bone cement and an outlet (40) for expressing the cement into a vertebral body. The handle (26) extends from the sheath (24) and includes a vibration assembly (70) for agitating the cement. The method includes providing a bone cement source to the needle. The method further includes providing a vibration assembly associated with a handle of the needle, agitating the cement with the vibration assembly and injecting the cement through the sheath.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CEMENT DELIVERY NEEDLE

FIELD OF THE INVENTION

[0001] This application relates to an apparatus and system for performing vertebroplasty. In particular, this application relates to a surgical
5 needle for expressing bone cement into a vertebral body.

BACKGROUND OF THE INVENTION

[0002] Percutaneous vertebroplasty involves the injection of a bone cement or suitable biomaterial into a vertebral body via a percutaneous route under X-ray, ultrasonic, magnetic resonance imaging, or other visual
10 guidance. The cement is injected as a semi-liquid substance through a needle that has been inserted into the vertebral body, generally along a transpedicular or posterolateral approach. The three main indications for vertebroplasty are benign osteoporotic fractures, malignant metastatic disease and benign tumors of the bone. Traumatic fractures of weakened
15 bone or traumatic fractures of normal bone can also be treated by the methods described here. The bone cement materials injected into a vertebral body may be derivatives of polymethyl methacrylate (PMMA) or biologically active substances such as calcium triphosphate, calcium phosphate or hydroxyapatite or bone morphogenic protein (BMP).

[0003] Percutaneous vertebroplasty provides structural reinforcement of a vertebral body through injection, by a minimally invasive percutaneous approach, of bone cement material into the vertebral body. See, for example, Vasconcelos, C. et al., Is percutaneous vertebroplasty without pretreatment
20 venography safe? Evaluation of 205 consecutive procedures. *Am. J. Neuroradiol.* 2002, Jun-Jul; 23(6): 913-7. Percutaneous vertebroplasty can result in increased structural integrity, decreased micromotion at the fracture site, and possibly a destruction of pain fibers due to the heat of the bone
25 cement as it polymerizes and sets. Complete pain relief can be achieved in up to eighty percent of patients. The cement material should have properties

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that, when injected, can increase vertebral body stiffness and compressive strength. Any cement materials having these properties that are commonly known or become known to one of skill in the art may be used. The cement should be fluid enough to flow into fracture planes and to fuse them. Although
5 there is some debate about the appropriate thermal properties, it is believed by some that the heating effect can be beneficial and cause death to local nerve endings involved in pain stimulation. It is generally accepted that most pain relief is achieved due to increased structural integrity.

[0004] When performing vertebroplasty, a needle of an appropriate
10 gauge (for example, an eleven gauge or thirteen gauge in a smaller vertebral body) is passed down the pedicle until it enters the vertebral body and reaches the junction of the anterior and middle thirds. The needle is inserted at a suitable angle and passed through the periosteum, down the pedicle and into the vertebral body. Insertion of the needle may require a large applied
15 force. For example, a large force may be required when entering the cortex and in the transition from the pedicle to the vertebral body.

[0005] A suitable cement material is prepared, injected through the
needle and into the vertebral body, under lateral X-ray projection fluoroscopy imaging. Injection of the cement continues until adequate vertebral filling is
20 achieved. The injection is discontinued if the cement starts to extend into some unwanted location such as the disc space or towards the posterior quarter of the vertebral body, where the risk of epidural venous filling and hence spinal cord compression is greatest.

[0006] Exemplary needles for use in vertebroplasty are disclosed in
25 U.S. Patent No. 6,749,595, which is incorporated herein by reference. Typically, an injector system or a syringe may be attached to the needle for pressurized delivery of the cement to the vertebral body. Due to the high pressure used to inject the cement into the vertebral body, complications of vertebroplasty include a risk of extravasation of cement into the venous
30 system and further embolization to the lungs. These complications can cause cord compression and paralysis or pulmonary embolism and death. Murphy et al., A Review of Complications Associated with Vertebroplasty and

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Kyphoplasty as Reported to the Food and Drug Administration Medical Device Related Web Site, *Journal of Vascular and Interventional Radiology*, in press.

[0007] Thus, a need exists for a cement delivery apparatus that can withstand the rigors of insertion into a patient undergoing percutaneous vertebroplasty and that allows for delivery cement in a controlled manner to avoid complications associated with high pressure delivery of the cement to the vertebral body.

BRIEF SUMMARY OF THE INVENTION

[0008] This application provides a cement delivery needle apparatus that may be used to perform percutaneous vertebroplasty. The cement delivery needle apparatus may include a sheath and a handle. The sheath may have an inlet to receive a bone cement and an outlet for expressing the cement into a vertebral body. The handle extends from the sheath and may include a vibration assembly for agitating the cement.

[0009] A method of flowing a bone cement through a vertebroplasty needle apparatus is also provided. The method includes providing a bone cement source to the apparatus, providing a vibration assembly associated with a handle of the needle, agitating the cement with the vibration assembly and injecting the cement through the sheath.

[0010] A kit for use in performing vertebroplasty is also provided. The kit may include a local anesthesia assembly, a surgical cutting instrument, a cement assembly for injection into a vertebral body, and a cement delivery needle apparatus as described here. The cement delivery needle apparatus includes a sheath and a handle extending from the sheath, where the sheath has an inlet to receive a bone cement and an outlet for expressing the cement into a vertebral body, and the handle includes a vibration assembly for agitating the cement.

[0011] A cement delivery system is also provided. The cement delivery system includes a cement delivery needle, a sheath having an inlet to receive a bone cement and an outlet for expressing the cement into a vertebral body, a handle extending from the sheath, an injector having a barrel operably

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connected to the needle; and a vibration assembly disposed against the barrel for agitating the cement. Alternatively or in addition to an injector, the system may include a connector operably connected to the needle; and a vibration assembly disposed against the connector for agitating the cement

5 **[0012]** Advantages of the present invention will become more apparent to those skilled in the art from the following description of the preferred examples of the present invention that have been shown and described by way of illustration. As will be realized, the invention is capable of other and different examples, and its details are capable of modification in various
10 respects. Accordingly, the drawings and description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

The cement delivery needle apparatus will be described in further detail with reference to the figures.

15 **[0013]** Fig. 1 is a perspective view of a cement delivery needle apparatus;

[0014] Fig. 2A is a cross-sectional view of a handle of the needle apparatus shown in Fig. 1;

[0015] Fig. 2B is cross-sectional view of an alternative handle of the
20 needle apparatus shown in Fig. 1;

[0016] Fig. 3 is a perspective view of a cement delivery needle apparatus showing a syringe attached to the handle of the needle;

[0017] Fig. 4 is a perspective view of a cement delivery needle apparatus showing a connecting tubing attached to the handle of the needle;

25 **[0018]** Fig. 5 is a perspective view of another cement delivery needle apparatus;

[0019] Fig. 6 is a perspective view of yet another cement delivery needle apparatus;

[0020] Fig. 7 is a perspective view of another cement delivery needle
30 apparatus;

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[0021] Fig. 8 is a perspective view of another cement delivery needle apparatus;

[0022] Fig. 9A is an exploded partial perspective view of the needle apparatus of Fig. 1;

5 **[0023]** Fig. 9B is a partial perspective view of the needle apparatus of Fig. 1;

[0024] Fig. 9C is a partial perspective view of an alternative tip of the needle apparatus of Fig. 1;

[0025] Fig. 10 is a schematic representation of a kit for vertebroplasty;

10 **[0026]** Fig. 11 is a lateral view of 3 vertebrae where the middle vertebra has a condition suitable for treatment by vertebroplasty;

[0027] Fig. 12 is an axial view of the compressed vertebra through line III-III of Fig. 9;

15 **[0028]** Fig. 13A is an axial view of the vertebra in Fig. 12 showing the insertion of the cement delivery needle apparatus in Fig. 1 in a transpedicular approach;

[0029] Fig. 13B is an axial view of the vertebra in Fig. 12 showing the insertion of the cement delivery needle apparatus in Fig. 1 in a lateral approach;

20 **[0030]** Fig. 13C is an axial view of the vertebra in Fig. 12 showing the insertion of the cement delivery needle apparatus in Fig. 1 in a parapedicular approach;

25 **[0031]** Fig. 14A is an axial view of the vertebra in Fig. 12 showing the insertion of the cement delivery needle apparatus in Fig. 1 to the transition from the right pedicle to the vertebral body;

[0032] Fig. 14B is an axial view of the vertebra in Fig. 12 showing the insertion of the cement delivery needle apparatus in Fig. 1 inserted into the vertebral body; and

30 **[0033]** Fig. 15 is an axial view of the vertebra in Fig. 12 showing the insertion of the cement delivery needle apparatus in Fig. 1 inserted into the vertebral body where the insert is removed from the sheath and cement is delivered to the vertebral body.

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DETAILED DESCRIPTION OF THE INVENTION

[0034] A cement delivery needle apparatus **20** is shown in Fig. **1**. The needle apparatus **20** may be used for expressing a bone cement into a target site, for example, a vertebral body. By way of example, bone cement materials include, but are not limited to, polymethyl methacrylate (PMMA) and biologically active substances such as calcium triphosphate, calcium phosphate, hydroxyapatite or bone morphogenic protein (BMP). Portions of the needle apparatus **20** may be constructed of surgical grade stainless steel, but other suitable materials known to one of skill in the art, that are also compatible with magnetic resonance imaging may be used.

[0035] The cement delivery needle apparatus **20** shown in the example of Fig. **1** includes a sheath **24**, a handle **26** and an insert **28** receivably removable within the sheath **24**. The insert **28** is receivable within the sheath **24** for insertion of the needle apparatus **20** into a vertebral body **32** via a percutaneous route. The insert **28** is removable from the sheath **24** to facilitate the injection of a cement **36** into a vertebral body **32**.

[0036] The sheath **24** may be a generally a hollow cylinder with an interior **38**, an outlet **40** and an inlet **44**. The sheath **24** may be cylindrically centered about an axis **46** and, as shown in the example in Fig. **1**, the cross-sectional area of interior **38** may not be reduced at the outlet **40**. As shown, the outlet **40** may be beveled such that the outlet **40** presents a single planar face **48**. The planar face **48** may be at an angle from about 15° to about 75° to axis **46**, for example, about 30° to about 60°. However, the planar face **48** may be at any angle.

[0037] As shown in Figs. **9A** and **9B**, the insert **28** may be generally cylindrical with a tip **50**. The tip **50** may be beveled at substantially the same angle as the outlet **40** of the sheath **24** creating a beveled face **80**. When the insert **28** is received within the sheath **24**, the insert **28** may be oriented such that the tip **50** is flush with the outlet **40**. As shown in Fig. **9B**, the planar face **48** may be aligned with the beveled face **80**.

[0038] Fig. **9C** illustrates an alternative insert **24a** and sheath **28a** similar to the insert **24** and sheath **28** described above and given the same

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numeral with the suffix a. The sheath **24a** is cylindrically centered about axis **46a** and may include three substantially equal, inwardly beveled surfaces **48a** defining an outlet **40a**. The sheath **24a** may include three sharp points **49a** at outlet **40a**. Each sharp point **49a** may be present at each intersection of two beveled surfaces **48a**. Each beveled surface **48a** is at about the same angle to axis **46a**. Each planar face **46a** may be about 15° to about 75° to axis **46a**, for example, about 30° to about 60° and about 45°. However, the planar face **48a** may be at any angle.

[0039] The insert **28a** is generally cylindrical with a tip **72a**. The tip **72a** has three substantially equal, inwardly beveled faces **80a**. Each face **80a** is beveled at substantially the same angle as beveled surfaces **48a**. Thus, all three beveled faces **80a** intersect at a leading point **51a** that protrudes from the sheath **24a**. When the insert **28a** is received within sheath **24a**, insert **28a** can be oriented such that each of the beveled faces **80a** is aligned with one of the beveled surfaces **48a**. The bevel angle is substantially similar between the insert **28a** and the sheath **24a**, thus there is no step from the tip **72a** to the sheath **24a**, to present three continuous beveled faces from sheath **24a** to tip **72a**. Exemplary needles having the insert **24**, **24a** and the sheath **28**, **28a** may be in the Osteo-Site® bone biopsy needle sets, including the Murphy Side Bevel/Back M1M and Murphy Diamond Bevel M2 available from Cook, Incorporated, Bloomington, IN and are described in U.S. 6,749,595.

[0040] The inlet **44** of the sheath **24** may be fixed to the handle **26** for grasping by the operator as shown in Fig. 1. The inlet **44** may be fixed to the handle **26** by friction fit or other means known to one of skill in the art. The handle **26** may be a molded polymer, but other material and processes are also contemplated.

[0041] The handle **26** may be any shape suitable for grasping by an operator. **Figs. 2A** and **2B** illustrate cross sectional views of two exemplary shapes for the handle **26**. As shown in Fig. 1, for example, the handle **26** may have two wings **56** for grasping. A connector **60** may be formed within the handle **26**. The connector **60** may be a female Luer connector. The connector **60** may have an externally threaded center post **64** and internal

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sleeves **66**. The center post **64** may have a hollow interior **68** that is aligned with and extends from the interior **38** of the sheath **24**, forming a continuous cylindrical hollow from the handle **26** to the outlet **40**.

[0042] The handle **26** shown in Fig. 1 further may include a vibration assembly **70** operably connected to the handle **26** for agitating the cement **36** for injection of the cement **36** into the vertebral body **32** through the sheath **24**. The vibration assembly **70** may be constructed as part of the handle **26**, for example, but not limited to integrally molding the vibration assembly **70** at least partially into the handle **26**. Alternatively, the vibration assembly **70** may be removably connected to the handle **26** once the needle apparatus **20** is inserted into the vertebral body **32**. (See Fig. 6.) The cement **36** may be agitated prior to injection, during injection or any combinations thereof.

[0043] As shown in Fig. 1, the vibration assembly **70** may include a chamber **72** surrounding the center post **64** of the handle **26**. The chamber **72** may be formed integral with the handle **26**. The chamber **72** may contain vibrational member **74**, for example, a dense metallic spherically shaped body, such as a ball bearing. A plurality of vibrational members **74** may be in the chamber **72** as shown in Fig. 3. The vibrational member(s) **74** and the chamber **72** may be radiolucent. Other vibrational members known to one of skill in the art, such as a roller that may be cylindrical, tapered, or spherically shaped, may be used in the chamber **72**. The chamber **72** may further include an inlet port **76** and an outlet port **78**. Alternatively, a plurality of outlet ports **78** may exit from the chamber **72** (as shown in Fig. 3). The ports **76**, **78** may be formed in the handle **26** and connect to the chamber **72**. The inlet port may include a Luer connector **80** for attachment of tubing **82** connected to a compressed air source or other energy source (not shown). In operation, compressed air enters the inlet port **76** to cause the vibrational member **74** to vibrate and oscillate within the chamber **72**, vibration of the chamber **72** provides vibration to the post **64** and any body attached to the vibration assembly **70**. The pressurized air flow is from inlet port **76** to the chamber **72** and out the outlet port **78**. Pressurized air may be provided by any source known to one of skill in the art. The pressurized air source may be removably

connected via tubing **82** or any other means known to one of skill in the art. The connection of the tubing **82** to the inlet **76** may occur before or after placement of the needle **20** in the vertebral body **32**. For example, connection after the placement of the needle **20** may minimize any obscuring of the target site for the needle **20** insertion by any radiodense materials in the needle **20**. The handle **26** or tubing **82** may further include a switch **81** for controlling the supply of the air flow. The switch **81** may include on and off positions.

[0044] The connector **60** of the handle **26** of the needle **20** may releasably receive a plurality of attachments. As shown in Fig. 1, a complimentary connector **84** may be releasably attached to the connector **60** of the handle **26**. The connector **84** may be connected to the insert **28** at an end **54** of the insert **28**. The connector **84** also may be internally threaded to receive the externally threaded center post **64** of the connector **60** when the insert **28** is received within the sheath **24**. The connector **84** may include external locking arms **88** that are receivable by sleeves **66** when locking the insert **28** within the sheath **24**. For example, the connector **60** and the complimentary connector **84** may be Luer locks, however, the connector **60** and the complimentary connector **84** may be any releasable attachment known to one of skill in the art.

[0045] An injector **90** may also be releasably attached to the connector **60** of the handle **26** of the needle apparatus **20** as shown in Fig. 3. The injector **90** may be any suitable part for cement delivery through the hollow interior **68** of the handle **26** and the sheath **24** into the vertebral body **32**. The injector **90** may include a tapered barrel **93** as shown in Fig. 3B where the barrel **93** tapers to a connector **95**, such as a Luer connector, or any connector known to one of skill in the art. For example, the injector **90** may be a syringe **92** containing cement **36** for delivery to the vertebral body **32**. Exemplary syringes may be found in the Osteo-Force[®] High Pressure Injector Set, available from Cook Incorporated, Bloomington, IN. The Medallion Syringe from Merit Medical Systems Inc., South Jordan, UT and the DynaTorque Injector from Parallax Medical, Inc., Mountain View, CA. are also exemplary syringes that may be used.

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[0046] The syringe **92** may include a complementary connector **94** at an end **96**, such as a Luer connector, for releasable attachment of the syringe **92** to the threaded center post **64** of the connector **60**. The syringe **92** also may include a plunger **98** for expressing the cement **36** from the syringe **92** into the hollow interior **68** of the center post **64** through the interior **38** of the sheath **24** into the vertebral body **32**. Pressure to express the cement **36** from the syringe **92** may be generated by hand or other application of force to the plunger **98**.

[0047] As shown in Fig. **4**, a connecting tube **103** may be removably attached to the connector **60** of the handle **26**. A syringe **105** containing the cement **36** may be removably attached to the connecting tube **103**. The attachments between the connecting tube **103**, the syringe **105** and the connector **60** may be Luer connectors or any connectors known to one of skill in the art.

[0048] As shown in Fig. **5**, a cement delivery needle apparatus **200**, similar to the cement delivery needle apparatus **20**, may include a handle **226** having a vibration assembly **270** operably connected to the handle **226** for agitating the cement **36** for injection of the cement **36** into the vertebral body **32** through the sheath **224**. The vibration assembly **270** may be constructed as part of the handle **226**, for example, but not limited to integrally molding the vibration assembly **270** at least partially into the handle **226**. Alternatively, the vibration assembly **270** may be removably connected to the handle **226** once the needle **200** is inserted into the vertebral body **32**. The cement **36** may be agitated prior to injection, during injection or any combinations thereof.

[0049] The vibration assembly **270** may include an arm **274**, which can be mounted in various ways within the handle **226** to provide vibration to the post **264** and any body attached to the vibration assembly **270**. The arm **274** may be driven by a motor **276** that is actuated by a driver assembly **278** located in the handle **226**. For example, the motor **276** and the driver assembly **278** may be balanced in weight on either side of the handle **226** to assist the operator. As shown in Fig. **5**, the driver assembly **278** may include at least one battery **280** and a cable **282** connected to the motor.

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[0050] Alternatively, power may be provided by an electrical source external to the needle apparatus **200**. The motor **276** may be electromagnetic, mechanical and/or electromechanical, or any type of motor known to one of skill in the art. A switch **286** may be provided on the handle **226** to control the movement of the vibration assembly **270**. The switch **286** may control on/off movement of the arm **274** or the switch **286** may also control the speed with which the arm **274** provides vibration.

[0051] Similar to the handle **26** of the needle **20**, the handle **226** of the needle **200** shown in Fig. **5** may include a connector **260** that may releasably receive a plurality of attachments. As described above for the connector **60**, the connector **260** may releasably receive attachments by way of example, but not limited to, such as a connector having an insert, a syringe, and connecting tubing.

[0052] Another cement delivery needle apparatus **300** is shown in Fig. **6**. As described above, the vibration assembly may be removably connected to the handle. Fig. **6** illustrates the needle apparatus **300** prior to the attachment of the vibration assembly **370**. As shown in this example, the needle apparatus **300** includes a sheath **324**, a handle **326** and an insert **328** that is slidably removable from the sheath **324**. The handle **326** further includes a vibration assembly attachment site **362** for the attachment of the vibration assembly **370**. The vibration assembly **370** may be attached to the site **362** at any time, *i.e.*, prior to use or during use of the needle apparatus **300**, and the attachment of the vibration assembly **370** does not interfere with use of the needle apparatus **300** by the operator. As shown in Fig. **6**, the removably attachable vibration assembly **370** may include a chamber **372** that may be in two or more sections **372a** and **372b**. The sections may fit together to contact the handle **326** and have a shape complimentary to the handle **326** to, for example, surround the handle **326** for providing vibration to a post **364** of the handle **326**. Alternatively, the chamber **372** may be a single unit and of any shape that can be mounted on the handle **326** without interfering with the operation of the needle apparatus **300**. As shown, the section **372a** of the chamber **372** includes a vibrational member **374**, an inlet port **376** and an

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outlet port **378**. As described above, a compressed air source or other energy source may enter the inlet **376** to cause the vibrational member **374** to vibrate within the chamber **372**. Any of the vibration assemblies described herein may be removably attachable to the handle of the needle as can be understood by one of skill in the art.

[0053] A further cement delivery needle apparatus **500** is shown in Fig. 7. The needle apparatus **500** is similar to the needle shown in Figs. **3A** and **3B** where an injector **590** is connected to a handle **526**. As shown in Fig. 7, the needle apparatus **500** includes a vibration assembly **570** disposed against the injector **590** for agitating the cement **36** for injection of the cement **36** into the vertebral body **32** through the sheath **524**. The vibration assembly **570** may be constructed as part of the injector **590**, for example, but not limited to integrally molding the vibration assembly **570** at least partially into the injector **590**. Alternatively, the vibration assembly **570** may be removably connected to the injector **590** once the needle apparatus **500** is inserted into the vertebral body **32**. The cement **36** may be agitated prior to injection, during injection or any combinations thereof.

[0054] As shown in Fig. 7, the vibration assembly **570** may include a chamber **572** surrounding the injector **590**. The chamber **572** may contain vibrational member **574**, for example, a dense metallic spherically shaped body, such as a ball bearing. A plurality of vibrational members **574** may be in the chamber **572**. The vibrational member(s) **574** and the chamber **572** may be radiolucent. Other vibrational members known to one of skill in the art, such as a roller that may be cylindrical, tapered, or spherically shaped, may be used in the chamber **572**. The chamber **572** may further include an inlet port **576** and an outlet port **578**. Alternatively, a plurality of outlet ports **578** may exit from the chamber **572**, similar to the plurality of ports shown in Fig. 3. The inlet port may include a Luer connector **580** for attachment of tubing **82** connected to a compressed air source or other energy source (not shown). Operation of the vibration assembly is as described above. Alternatively, a vibration assembly similar to the vibration assembly **270** in Fig. 5 may be operatively connected to the injector **590**.

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[0055] A cement delivery needle apparatus **600** having a vibration assembly **670** that may be disposed against a connector **603** is shown in Fig. **8**. The vibration assembly **670** is similar to the vibration assemblies described above with the exception that the vibration assembly **670** is disposed against the connecting tube **603** instead of the injector **590** as described above and shown in FIG. **7**. Operation of the vibration assembly **670** is as described above. Alternatively, a vibration assembly similar to the vibration assembly **270** in Fig. **5** may be operatively connected to the connecting tube **603**.

[0056] The cement delivery needle apparatus **20, 200, 300, 500, 600** may be 10, 11, 13, or 14 gauge depending on where the needle is to be used. Generally, 10 or 11 gauge needles are used for delivery of cement to a vertebral body in a lumbar or sacral vertebra and 13 or 14 gauge needles are used for delivery of cement to a vertebral body in a thoracic or cervical vertebra. The cement delivery needle apparatus **20, 200, 300, 500, 600** may be about eight cm to about twenty cm in length. For example, the cement delivery needle apparatus **20, 200, 300, 500, 600** may be about ten cm to about fifteen cm in length. Thin walled, large lumen needles, having a similar outer diameter as the needles described above and an increased inner diameter may also be used. The insert **28** described above provides strength for insertion of the thin walled, large lumen needles. However, one of skill in the art will recognize that the size and proportions of the cement delivery needle apparatus **20, 200, 300, 500, 600** may vary depending on the vertebral body being filled and the subject. For example, the cement delivery needle apparatus **20, 200, 300, 500, 600** may be made as radiolucent as possible to assist the operator in positioning the needle apparatus **20, 200, 300, 500, 600** in the vertebral body **32**. The needle apparatus **20, 200, 300, 500, 600** may be reusable or disposable.

[0057] As shown in Fig. **10**, the needle apparatus **20, 200, 300, 500, 600** may be part of a kit **400** for performing vertebroplasty. Kit **400** may have a first tray **457** and a second tray **459**. Each tray **457, 459** may be housed within sterile packaging for storage until use and may include a local anesthesia assembly **461**, a surgical cutting instrument **471** such as a scalpel,

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a cement delivery needle, such as the needle apparatus **20**, **200**, **300**, **500**, **600** described, and a cement mixing assembly **481**, **482** respectively, for preparing the cement **36**. The anesthesia assembly **461** may include a vial of local anesthesia **463**, a syringe **465** for administering the anesthesia, a needle **467** for anesthesia aspiration and a long needle **469** for anesthesia injection.

[0058] The cement mixing assemblies **481** and **482** of the trays **457**, **459**, respectively, may have different components for preparing cement having different imaging properties. The mixing assembly **481** of the tray **457**, for example, may include a monomer liquid **483** in a vial, a monomer compatible aspiration syringe **484**, a monomer aspiration needle **485**, a mixing bowl **486**, a mixing spatula **488**, a polymer powder **490**, and a first opacifier **492**. The mixing assembly **482** of the tray **459** may include components similar to the mixing assembly **481** of the tray **457** such as a monomer liquid **502** in a vial, a monomer compatible aspiration syringe **504**, a monomer aspiration needle **505**, a mixing bowl **506**, a mixing spatula **508**, a polymer powder **510**. The mixing assembly **482** may also include an opacifier **512** that may be of a different density than the first opacifier **492** of the mixing assembly **481**. Alternatively, the densities of the opacifiers **492**, **512** may be the same. The components of the trays are described in detail in application serial number 09/594,685 which is incorporated by reference in its entirety herein. One of skill in the art will recognize that the trays **457**, **459** may contain additional or alternative components for performing vertebroplasty.

[0059] The use of the needle apparatus **20** to perform vertebroplasty on the vertebra **96** is shown in **Figs. 11-15**. As shown in **Fig. 12**, vertebra **96** has a right and left transverse process **104R**, **104L**, a right and left superior articular process **108R**, **108L**, and a spinous process **112** at the posterior of vertebra **96**. Right and left lamina **116R**, **116L** lie intermediate to the spinous process **112** and the superior articular processes **108R**, **108L**, respectively. Right and left pedicles **120R**, **120L** and lamina **116R**, **116L** cooperate to form a vertebral arch **124**. The vertebral body **32** is located at the anterior of the vertebra **96**, and is joined to the arch **124** at the pedicles **120R**, **120L**. The arch **124** and the vertebral body **32** define the spinal canal **128** through which

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the spinal cord **132** passes. A periosteum **136**, a layer of tissue, covers a cortex **138**. The cortex **138** is the outer surface of the vertebra **96**.

[0060] The patient is placed in the prone position so that the vertebra **96** is within the field of an imaging device such as an X-ray projection fluoroscopy imaging device. Other imaging devices can be used, as will occur to those of skill in the art. When the imaging device is "on", the vertebra **96** is projected onto a display. The skin overlying the vertebra **96** is prepped and draped in the usual manner with sterile technique, as will be understood by those of skill in the art. Instruments and supplies required for the vertebroplasty procedure may be supplied in the kit **400**. An anesthetic is injected into the skin, underlying fat and into the periosteum **136** of the pedicle to be entered. For explanatory purposes it is assumed that the right pedicle **120R** will be entered first. Next, a skin incision of about five millimeters is made using a scalpel, such as the scalpel **71** in the kit **400**.

[0061] At this point, the needle apparatus **20** is grasped by the operator. Typically, the needle **20** is grasped by the operator such that the palm of the operator's hand abuts the complementary connector **84** and the operator's fingers are folded around wings **56** of handle **26**. Thus, the sheath **24** with the insert **28** received therein, protrudes between the fingers of the operator.

[0062] As shown in Figs. **13-16**, the needle apparatus **20** is inserted into the incision and passed down the right pedicle **120R**, for example, until it enters the vertebral body **32** and reaches the junction of the anterior and middle thirds. The needle apparatus **20** is inserted until the tip **50** meets the periosteum **136**, as shown in Fig. **13A**. As shown in Figs. **13B** and **13C**, lateral and parapedicular approaches are also possible for insertion of the needle apparatus **20** into the vertebral body **32**. Additional applied force is then required to pass through the periosteum **136** and the cortex **138** and into the right pedicle **120R**. The needle apparatus **20** with the tip **50** is inserted further to the transition from the right pedicle **120R** to the vertebral body **32**, as shown in Fig. **14A** illustrating the transpedicular approach. Again, additional applied force is required to pass through the transition and into the

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vertebral body **32**. The needle apparatus **20** is further inserted until the tip **50** reaches the junction of the anterior and middle thirds of the vertebral body **32**, as shown in Fig. **14A**. Fig. **14B** illustrates needle apparatus **20** insertion for lateral and parapedicular approaches. At this point the complementary connector **84** may be released from the connector **60** and the insert **28** is slidably removed from the sheath **24**. The position of the sheath **24** is maintained such that the tip **50** is still in the vertebral body **32** after the insert **28** is removed from the sheath **24** as shown in Fig. **15**.

[0063] The cement **36** for strengthening the vertebral body **32** may then be prepared. The prepared cement **36** is inserted into the syringe **92** and the syringe **92** is releasably connected to the connector **60** of the handle **26**. Alternatively, the syringe **92** is releasably attached to the connecting tubing **105** which is releasably attached to the connector **60**.

[0064] The vibration assembly **70** on the handle **26** may be activated prior to the injection of the cement **36** through sheath **24** and into vertebral body **32**. The vibration assembly **70**, as shown in Fig. **1**, may be activated by supplying a source of compressed air to the inlet **76** that enters the chamber **72** to activate the vibrational member **74**. The flow of air continues out through the outlet **78**. The vibrational member **74** may oscillate within the chamber **72** causing vibration of the post **64** and the cement **36** flowing therethrough. The frequency of the oscillations may be such that the flow of the cement transitions from laminar flow to particulate ball bearing flow where the particles move more easily than the laminar flow. The frequency of the oscillation will vary with the chemical properties of the cement **36**, for example, the particular cement preparation, the amount of radiodense material added and the particle size. The vibration assembly **70** may be operational prior to or during injection of the cement **36** or both. The vibration assembly **70** improves the flow of the cement **36** to particulate, ball bearing flow and thus, reduces the amount of pressure required to inject the cement **36** from the syringe **92** through the hollow interior **68** of the handle **26** and through the sheath **24** into the vertebral body **32**. Without vibration of the cement, the intravertebral pressure exerted during injection may range from

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about 150 mm Hg (2.9 psi) with a hand crank injector to about 500mm Hg (9.7 psi) with a plunger type applicator. The injector device itself may be capable of generating pressure by hand of between 800 and 1400 psi. The pressure applied to the plunger **94** of the syringe **92** to express the cement **36** when using the vibration assembly **70** to agitate the cement **36** may be less than about 800 psi, for example less than about 700 psi. The decreased injection pressure may help avoid undesirable extrusion of the cement into the veins that may continue even after the pressure on the injector is removed when the cement is injected with an injector exerting greater than 1200 psi.

[0065] The direction of the cement **36** injected into the vertebral body **32** may be controlled as the cement **36** is ejected from the beveled outlet **40**. Thus, the sheath **24** may be turned to aim the beveled outlet **40** and thereby direct the flow of the cement **36** in the vertebral body **32**. As filling of the vertebral body **32** progresses, the sheath **24** may be rotated about the axis **46** to direct the cement **36** in a preferred direction or to direct the cement **36** away from a disc space of the vertebra **96**, as desired. Delivery of the cement **36** may be observed by an imaging device, including, for example, x-ray, ultrasonic, magnetic resonance or other visual guidance devices.

[0066] At this point, a decision may be made as to whether a sufficient quantity of the cement **36** has been injected. This decision is made using known criteria and is typically made by the radiologist, physician or other vertebroplasty professional who is performing the method. If it is determined that enough of the cement **36** has been injected to provide the desired strength to the vertebral body **32**, pressure by the user on the plunger is removed and the vibration assembly **70** may be turned off by stopping the flow of compressed air and the flow of the cement **36** stops. When the vibration of the vibration assembly **70** is stopped, the flow of the cement **36** returns to laminar flow thus requiring greater pressure, *i.e.*, greater than 800 psi, if the cement **36** is continued to be expressed. Once the desired amount of the cement **36** has been delivered to the vertebral body **32**, the treatment method is complete. If it is determined that not enough of the cement **36** has been injected into the vertebral body **32**, then a second injection may be

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performed by inserting the needle apparatus **20** through the other pedicle, in this case the left pedicle **120L**. For the second injection, the second density of the cement **36** may be used from the mixing assembly **482** of the kit **400**.

[0067] The use of the needle apparatus **200** shown in Fig. **5** may be similar to the use of the needle apparatus **20** described above with the exception of the operation of the vibration assembly **270**. As described above for the vibration assembly **70**, the vibration assembly **270** on the handle **226** may be activated prior to the injection of the cement **36**, during injection or both. Activation of the vibration assembly **270** may cause the flow of the cement **36** to transition from laminar flow to particulate, ball bearing flow. The vibration assembly **270** may be activated by the switch **286**. The vibrational speed of the assembly **270** may also be controlled by the switch **286**. When the switch **286** is "on", power may be supplied to the motor **276** from the driver assembly **278** to move the arm **274**. The arm **274** may provide vibration to the post **264** of the handle **226**. Once the desired amount of the cement **36** has been delivered to the vertebral body **32**, the switch **286** may be turned "off" and the pressure on the plunger removed to stop the flow of the cement **36**.

[0068] The use of the needle apparatus **300** shown in Fig. **6** may be similar to the use of the needle apparatus **20** described above with the exception of the attachment of the vibration assembly **370** to the handle **326**. The needle apparatus **300** may be inserted into the vertebral body as described above without having the vibration assembly **370** attached to the handle **326**. This may assist the operator in clearly viewing the vertebral body **32** for insertion and operation of the needle apparatus **300** until the needle has been positioned in the vertebral body **32**. The complementary connector **384** and the insert **328** may then be slidably removed from the sheath **324**. The vibrational assembly **370** may then be attached to the handle **326** while the sheath **324** remains in position in the vertebral body **32**. Operation of the vibration assembly **370** once the assembly is attached to the handle **326** may be as described above for the vibration assembly **70**.

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[0069] This application is not limited to the particular examples described above. The individual components of the described system may be combined in any suitable manner to practice the system according to the respective demands of the user. In addition, while various aspects of the invention have been described, it will be apparent to those of ordinary skill in the art that many more aspects and implementations are possible within the scope of the invention. Accordingly, the invention is not to be restricted except in light of the attached claims and their equivalents.

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Claims

1. A cement delivery needle apparatus comprising:

a sheath having an inlet to receive a bone cement and an outlet for expressing the cement into a vertebral body;

5 a handle extending from the sheath; and

a vibration assembly disposed with the handle for agitating the cement.

2. The needle apparatus of claim 1 further comprising a removable insert within at least a portion of the sheath.

10 3. The needle apparatus of claim 1 or 2 where the vibration assembly comprises an energy source operably connected to the vibration assembly.

4. The needle apparatus of any one of the preceding claims where the vibration assembly comprises a chamber surrounding a passageway through the handle, where the passageway is operably connected to the sheath.

15 5. The needle apparatus of claim 4 further comprising a vibrational member in the chamber, where the vibrational member oscillates in the chamber when the energy source is supplied to the chamber.

6. The needle apparatus of claim 5 where the vibrational member is adapted for rolling within the chamber.

20 7. The cement delivery apparatus according to any one of the preceding claims further comprising an injector removably connected to the handle for delivery of the cement to the sheath.

8. The needle apparatus according to any one of the preceding claims where the vibration assembly is removably connected to the handle.

25 9. The needle apparatus according to any one of claims 1-7 where the vibration assembly is at least partially integrally formed with the handle.

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10. The needle apparatus according to any one of the preceding claims where the vibration assembly comprises an arm for providing vibration to the handle.

11. The needle apparatus of claim 10 further comprising a motor for driving the arm.

12. The needle apparatus according to any one of the preceding claims where the cement comprises polymethyl methacrylate.

13. The needle apparatus according to any one of the preceding claims where the at least a portion of the needle apparatus is disposable.

14. The needle apparatus according to any one of the preceding claims where at least a portion of the needle apparatus is at least partially radiolucent.

15. A method for delivering bone cement to a target site, the method comprising the steps of:

providing a bone cement delivery needle apparatus according to any one of the preceding claims; and

agitating the cement for delivery to the target site.

16. A method of flowing a bone cement through a vertebroplasty needle apparatus comprising the steps of:

providing a bone cement source to the needle apparatus;

providing a vibration assembly associated with a handle of the needle;

agitating the cement with the vibration assembly; and

flowing the cement through the sheath.

17. The method according to claim 16 where the vibration assembly is removably attachable to the handle.

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18. The method according to any one of claims 16 or 17 further comprising the step of providing an energy source to the vibration assembly.

19. The method according to any one of claims 16-18 further comprising the step of providing pressure on an injector removably connected to the
5 needle assembly, the injector being configured for injecting the cement.

20. The method of claim 19 where the pressure is less than 800 psi.

21. The method of claim 19 where the pressure is less than 700 psi.

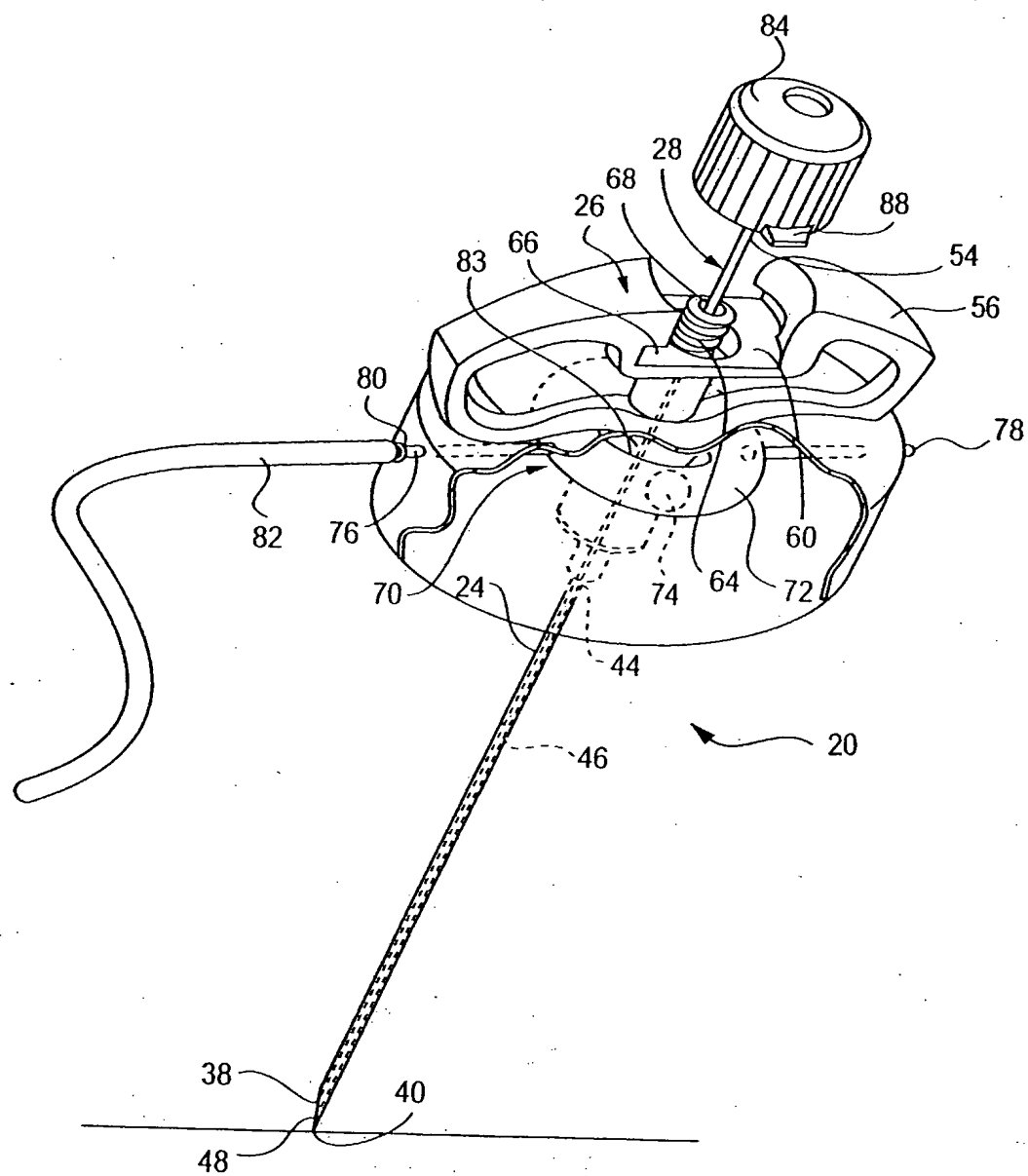


FIG. 1

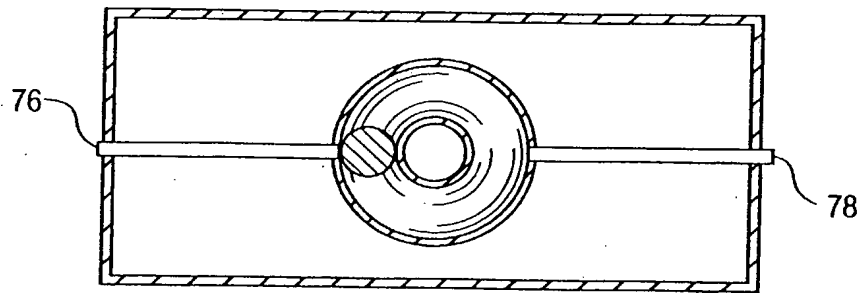


FIG. 2A

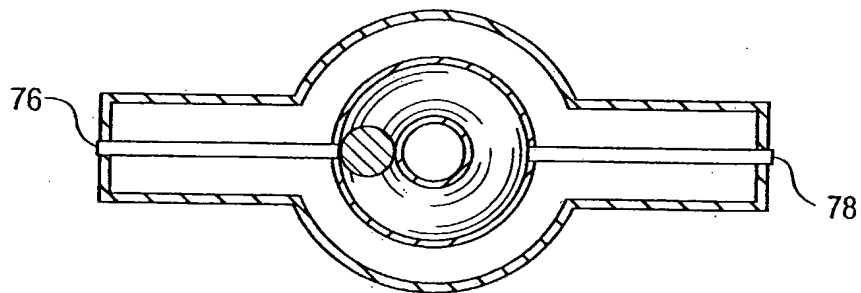


FIG. 2B

FIG. 3A

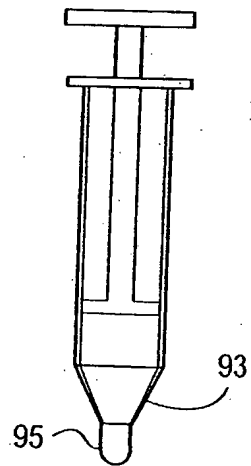
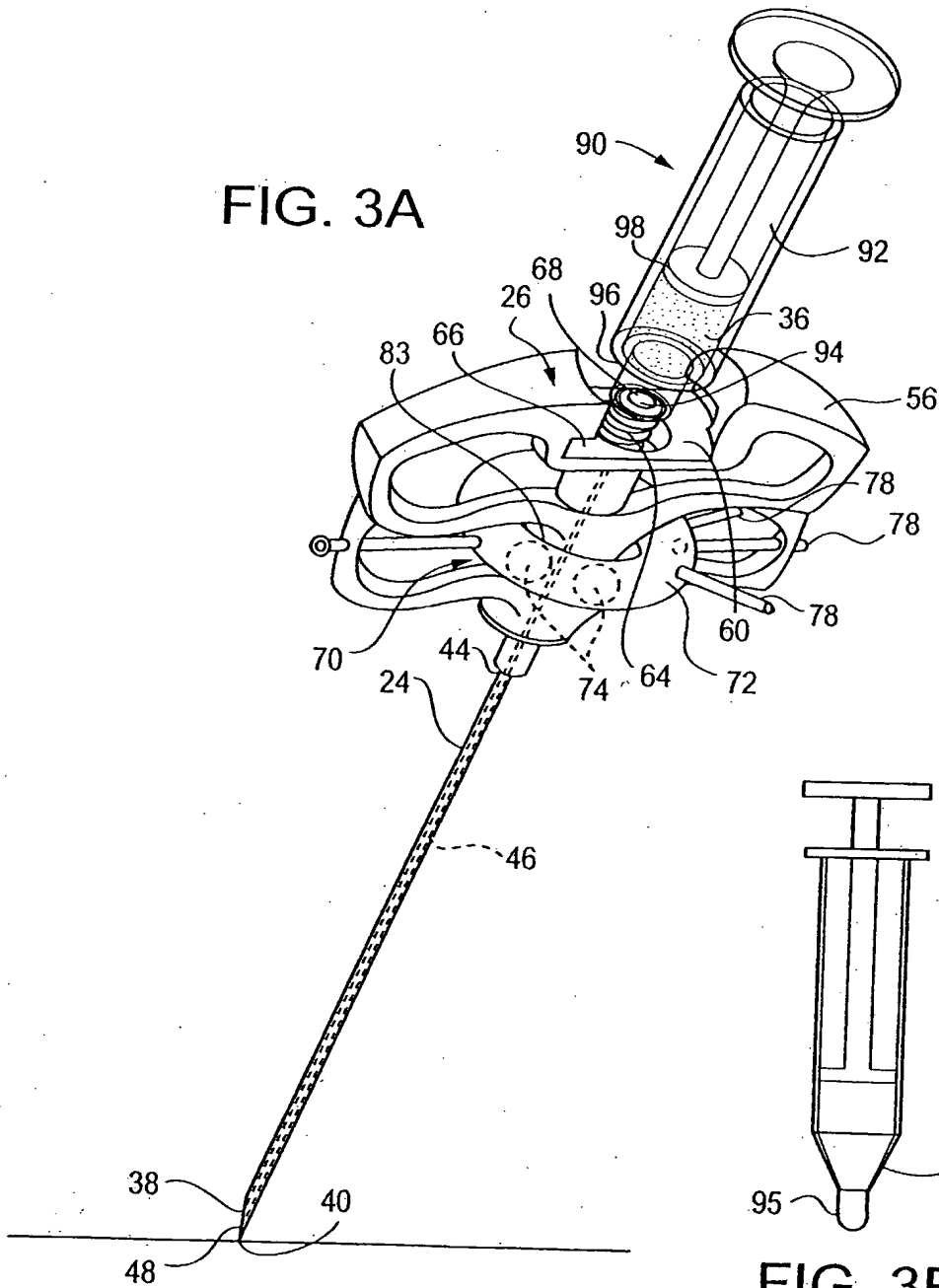
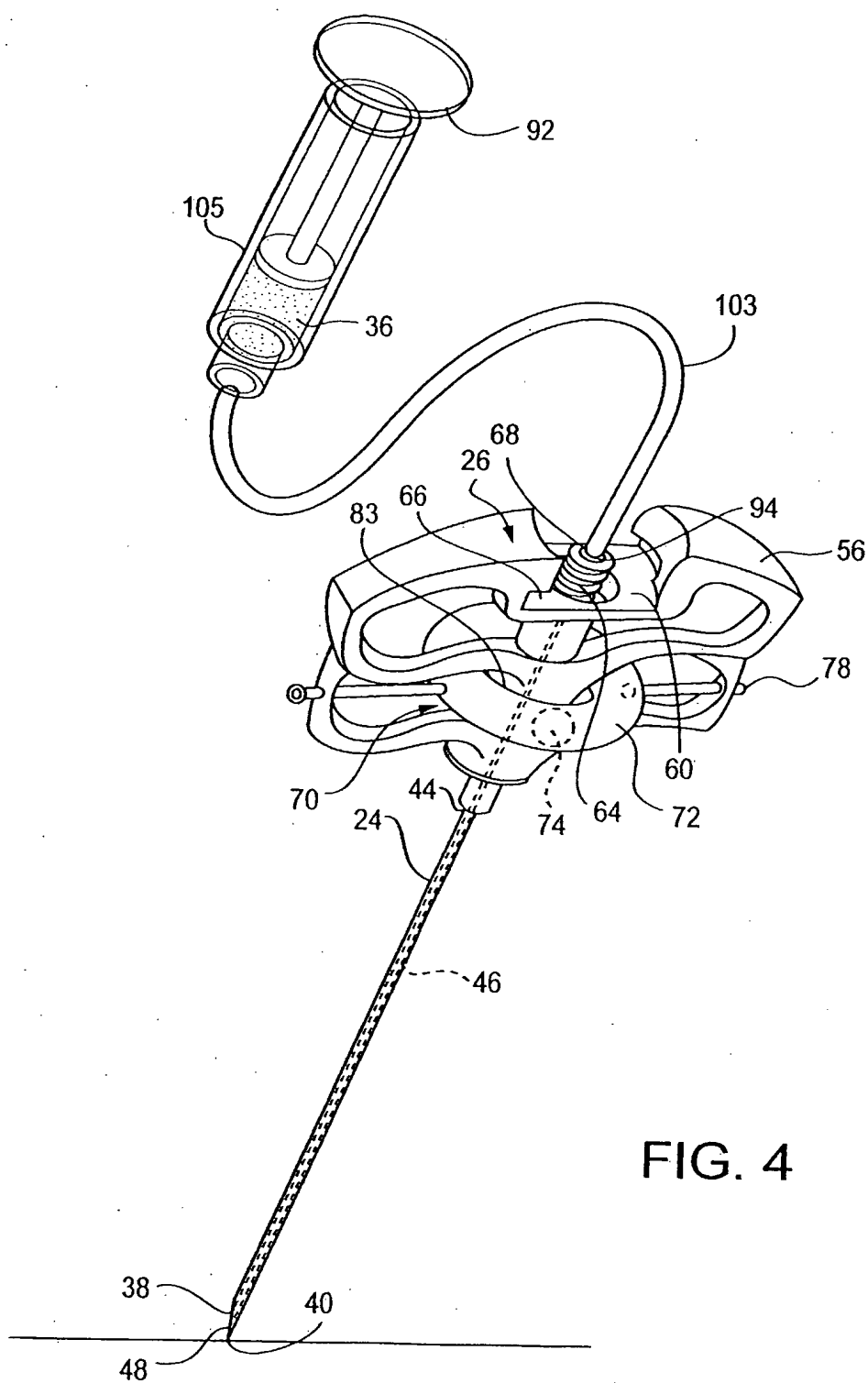


FIG. 3B



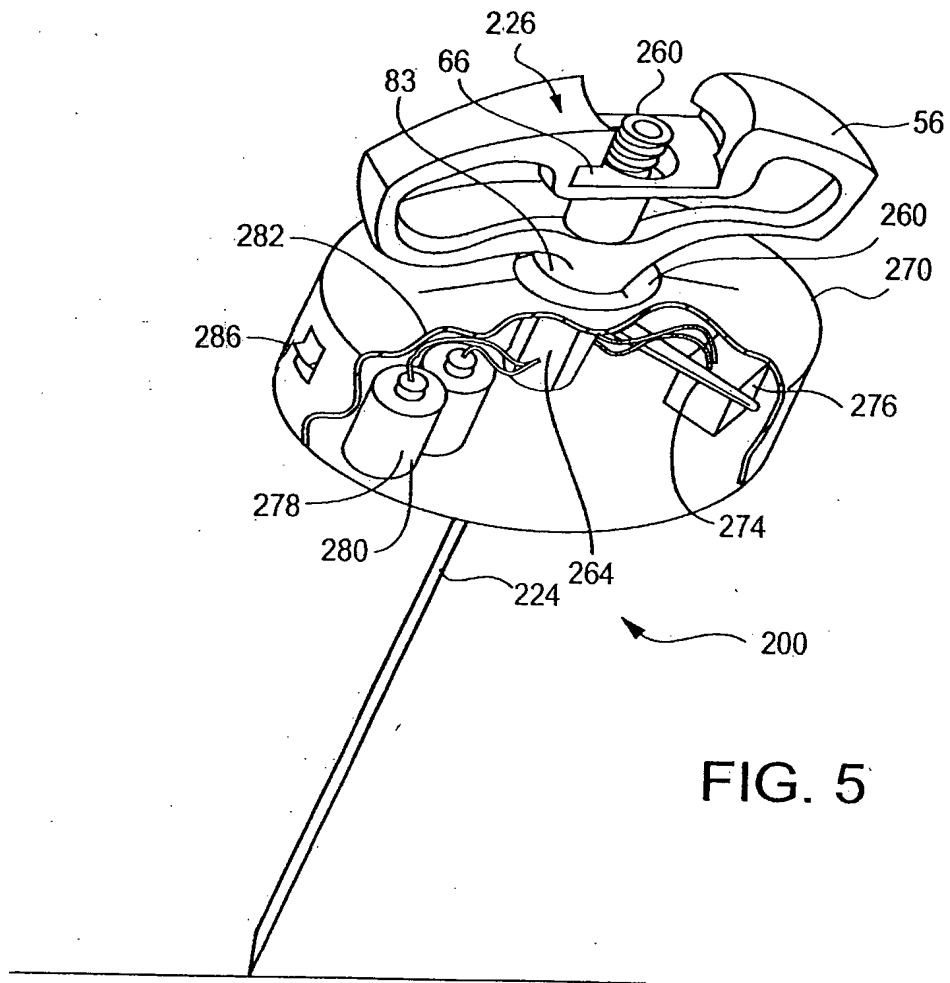


FIG. 5

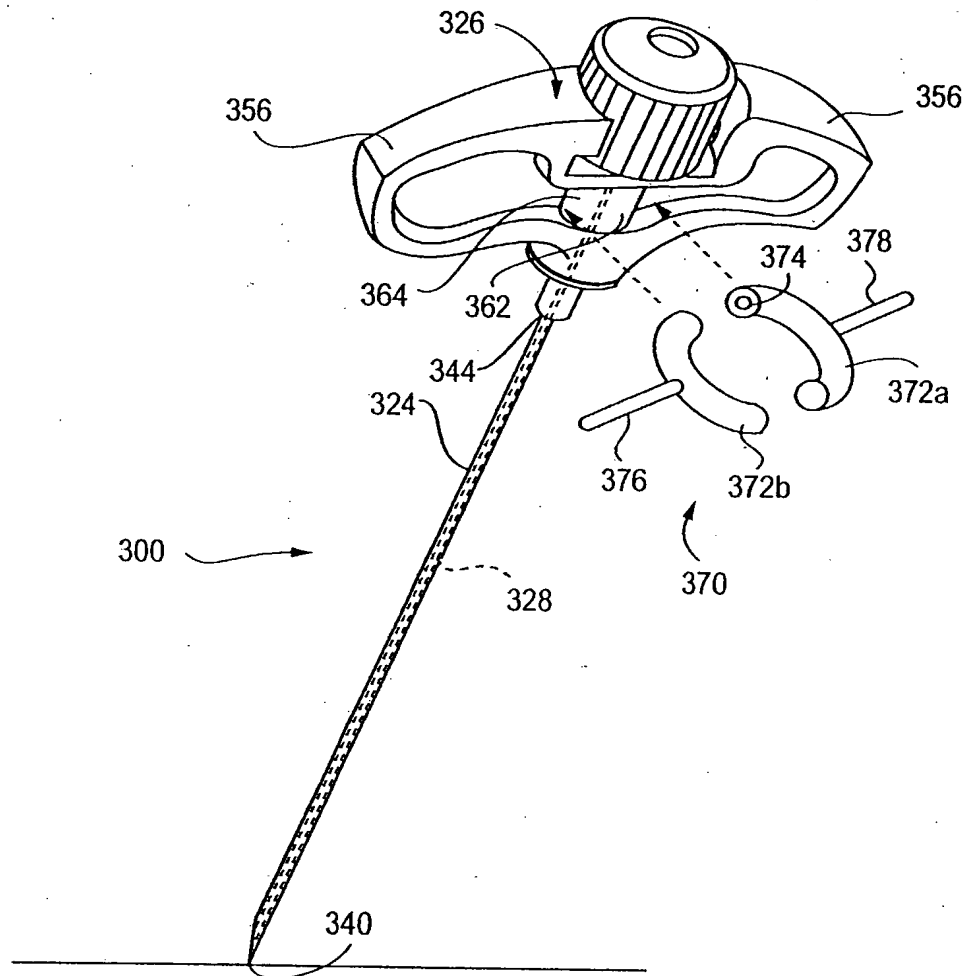
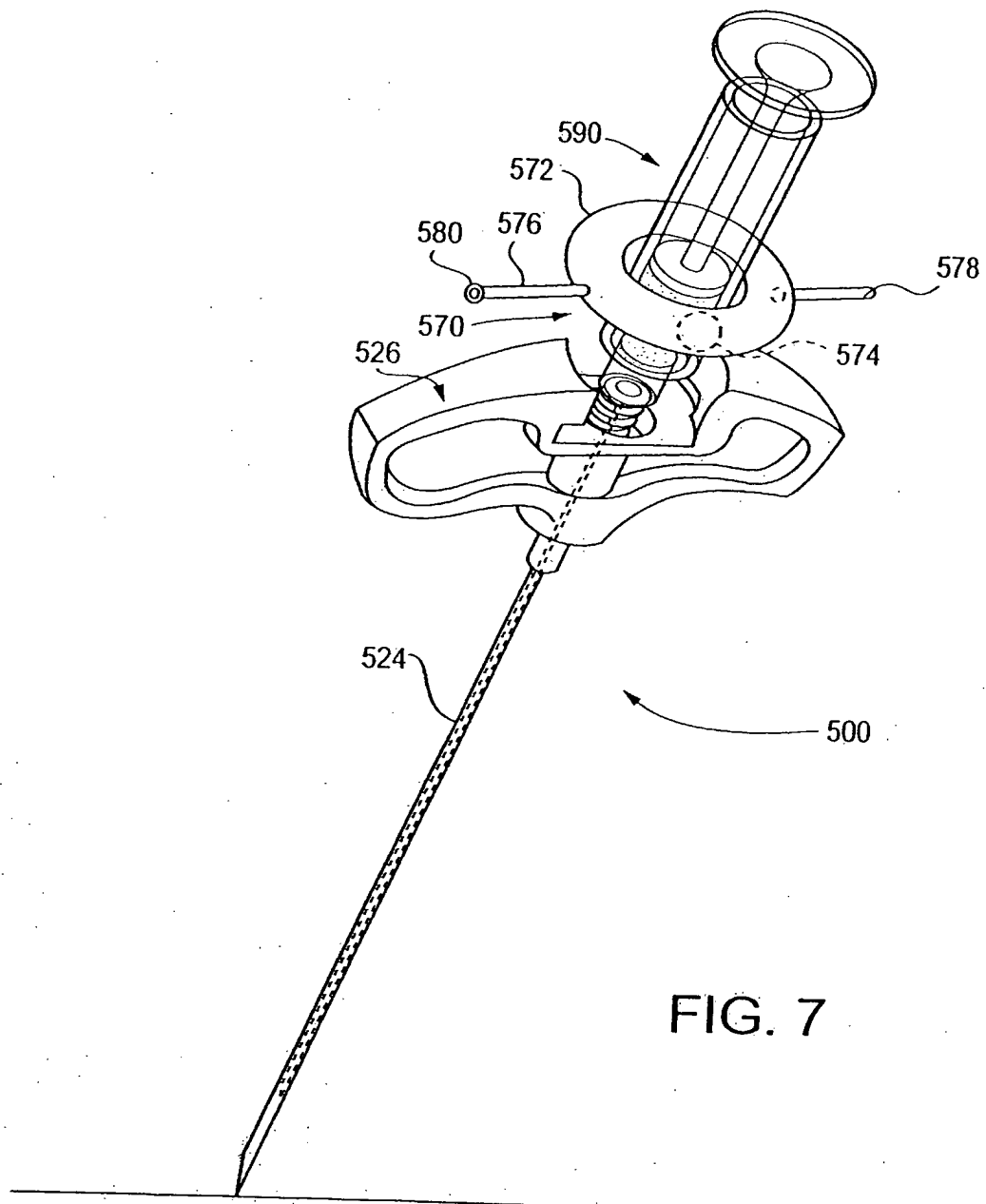
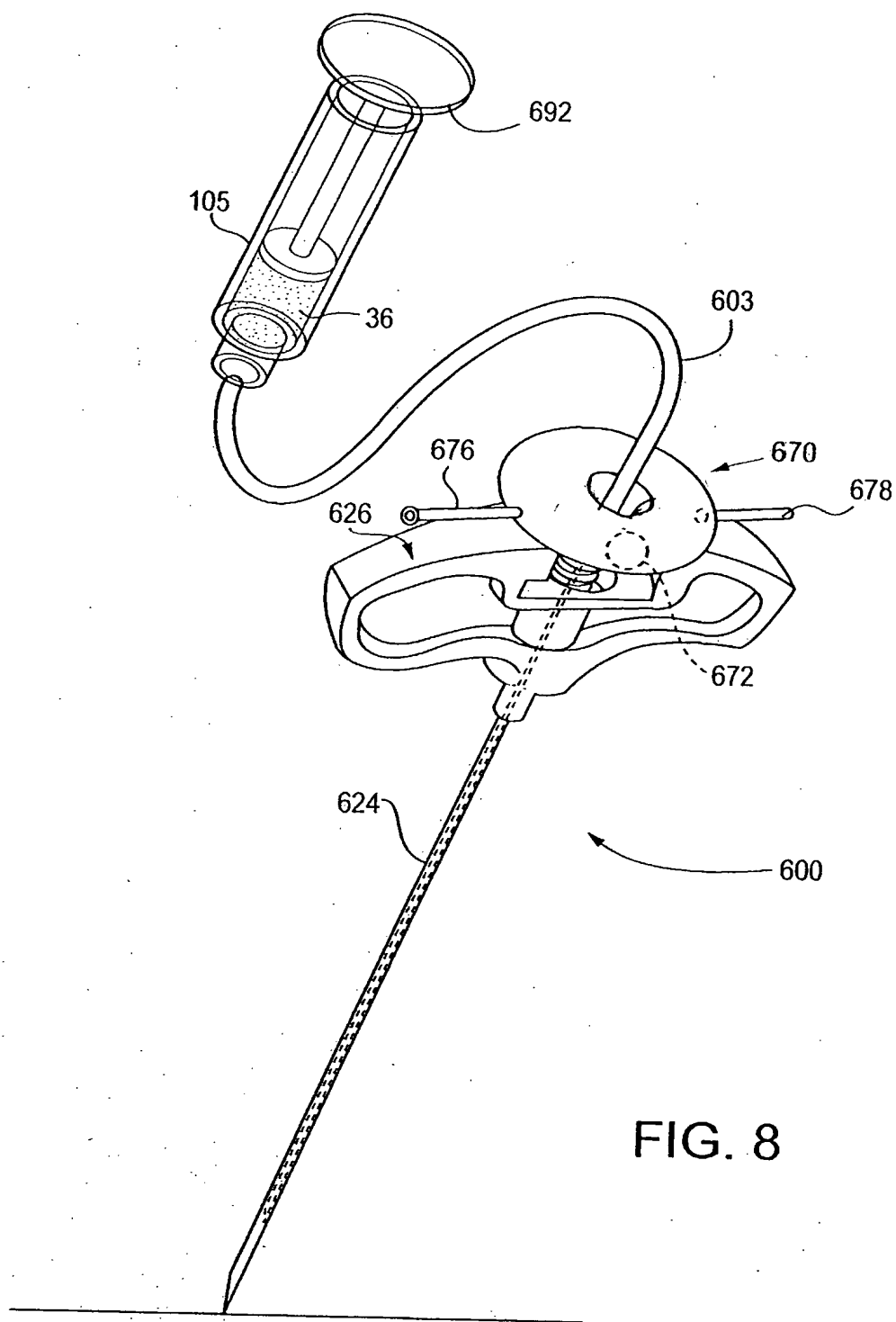
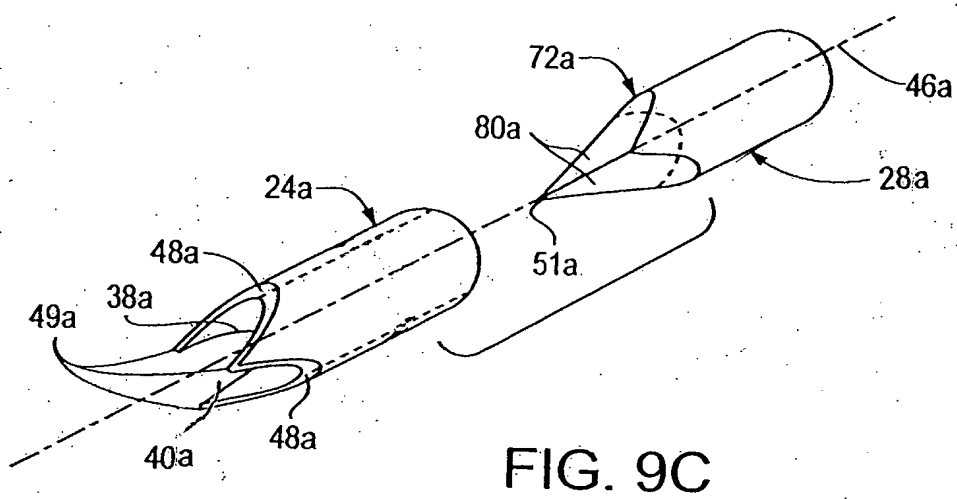
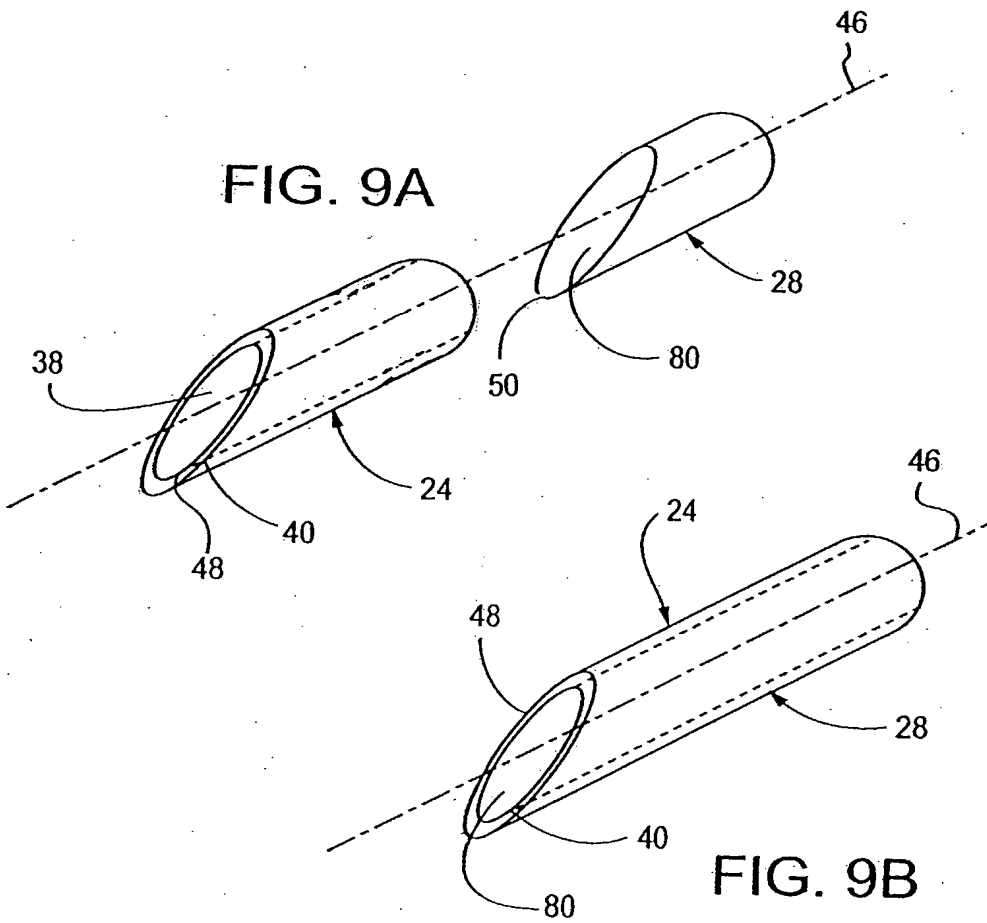


FIG. 6







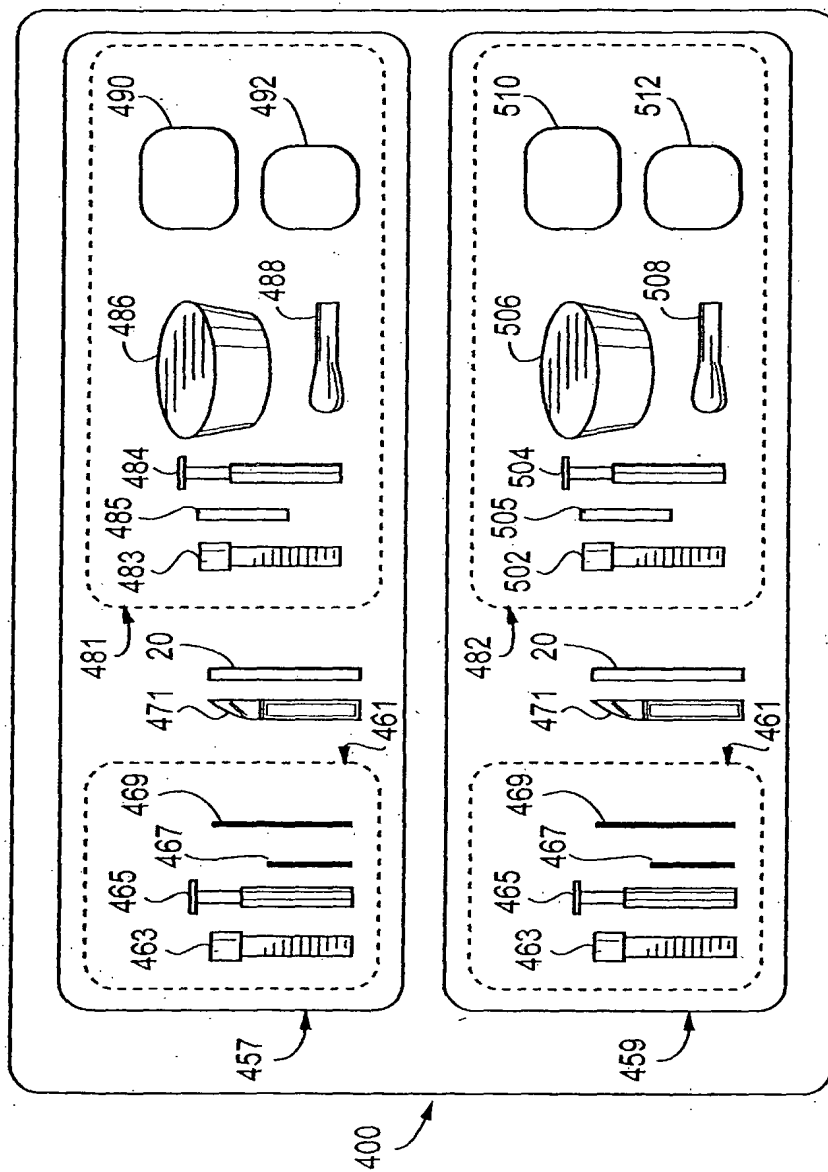


FIG. 10

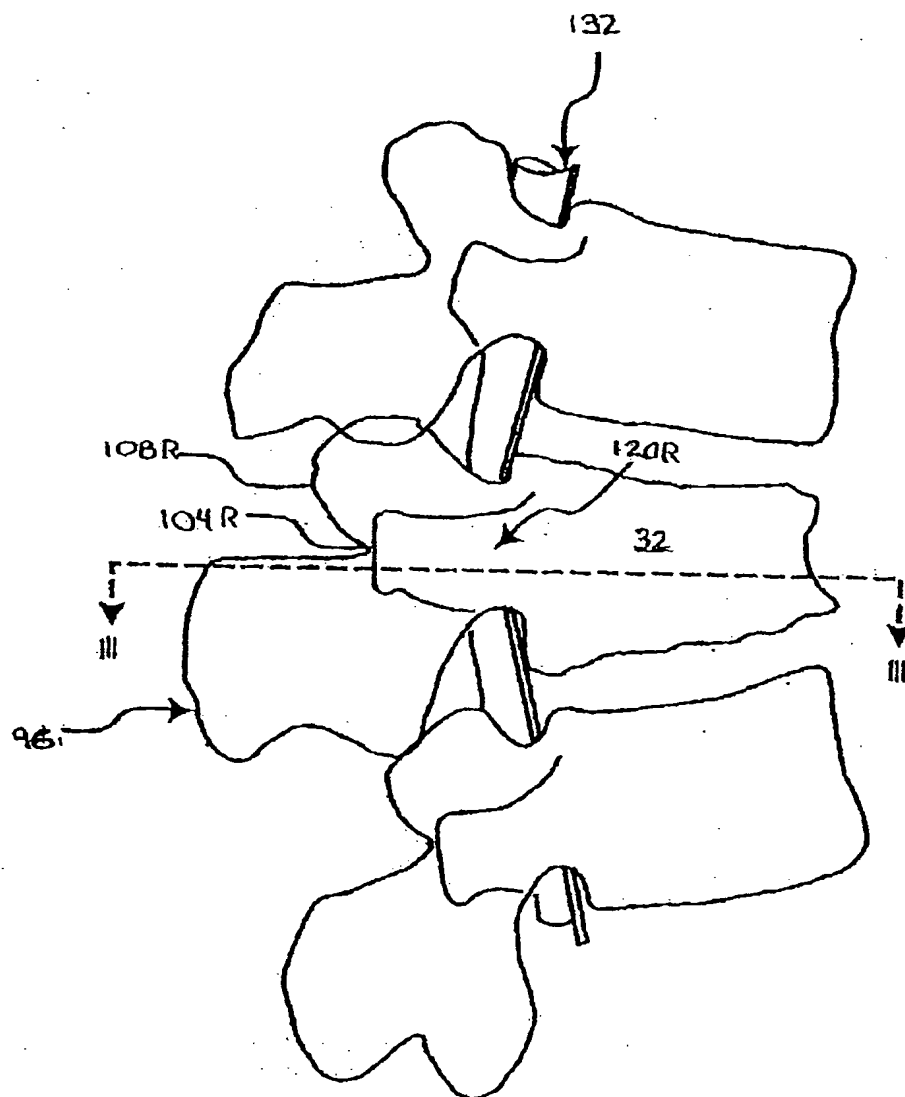


FIG. 11

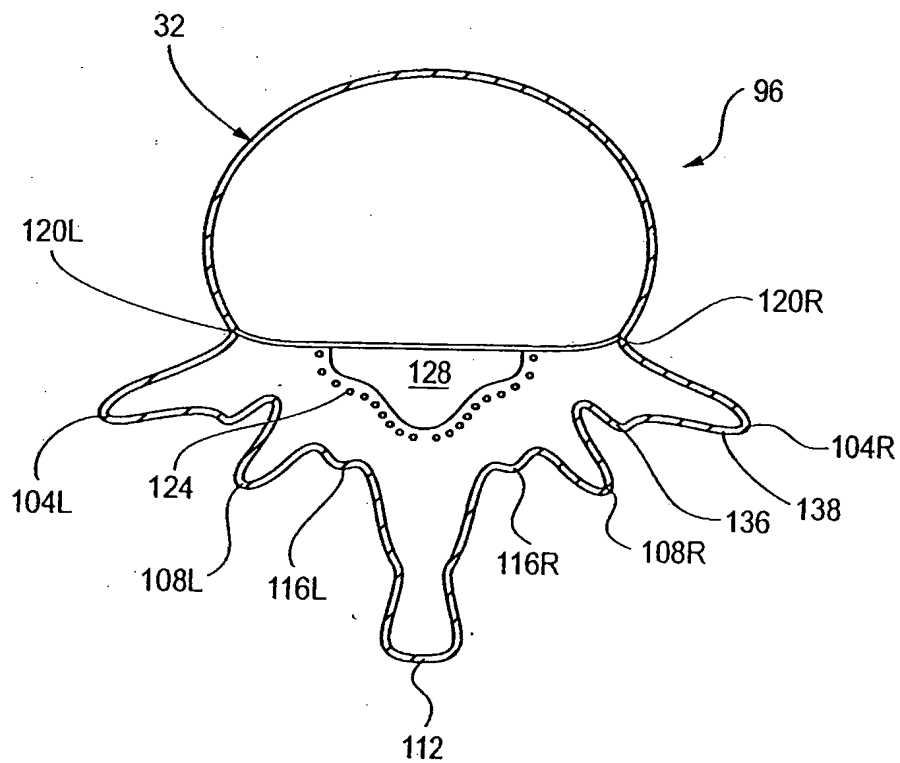
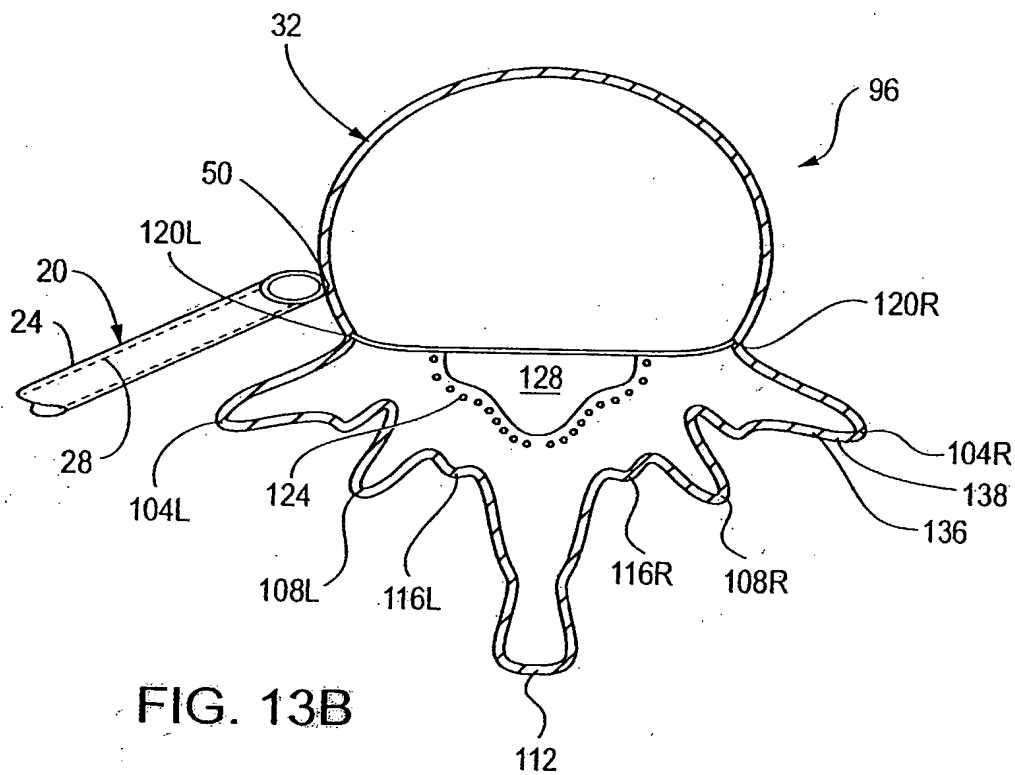
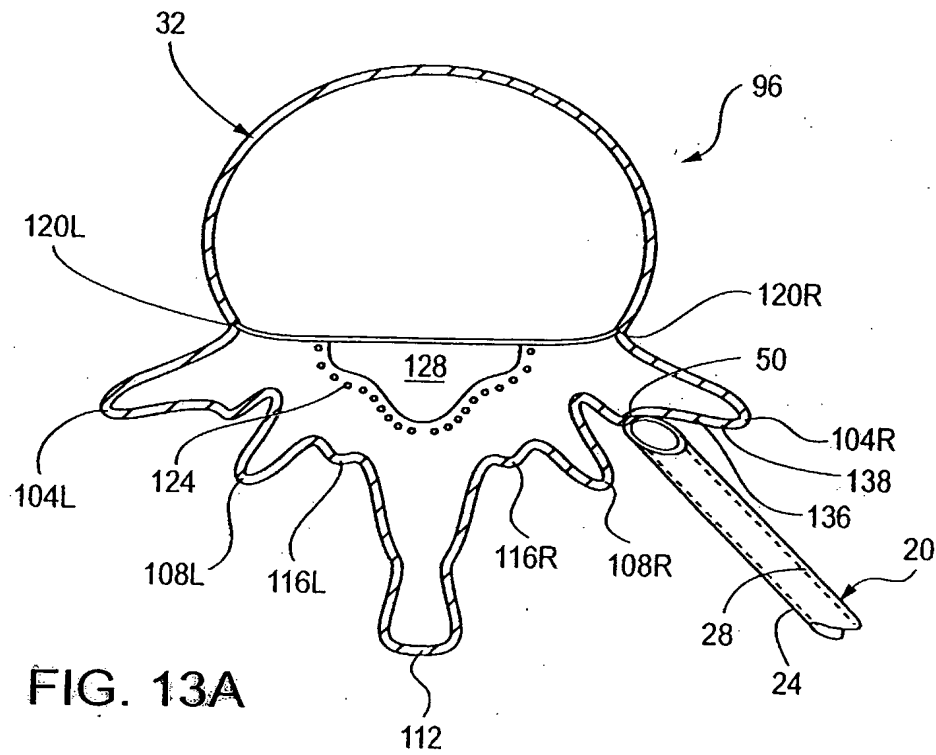
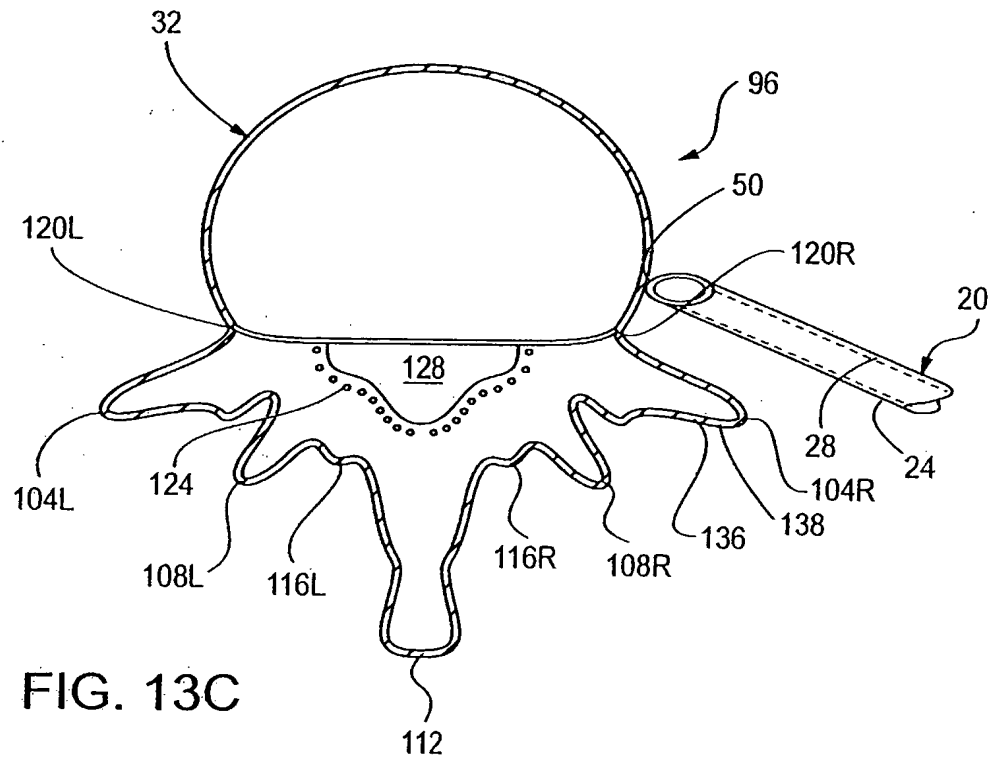
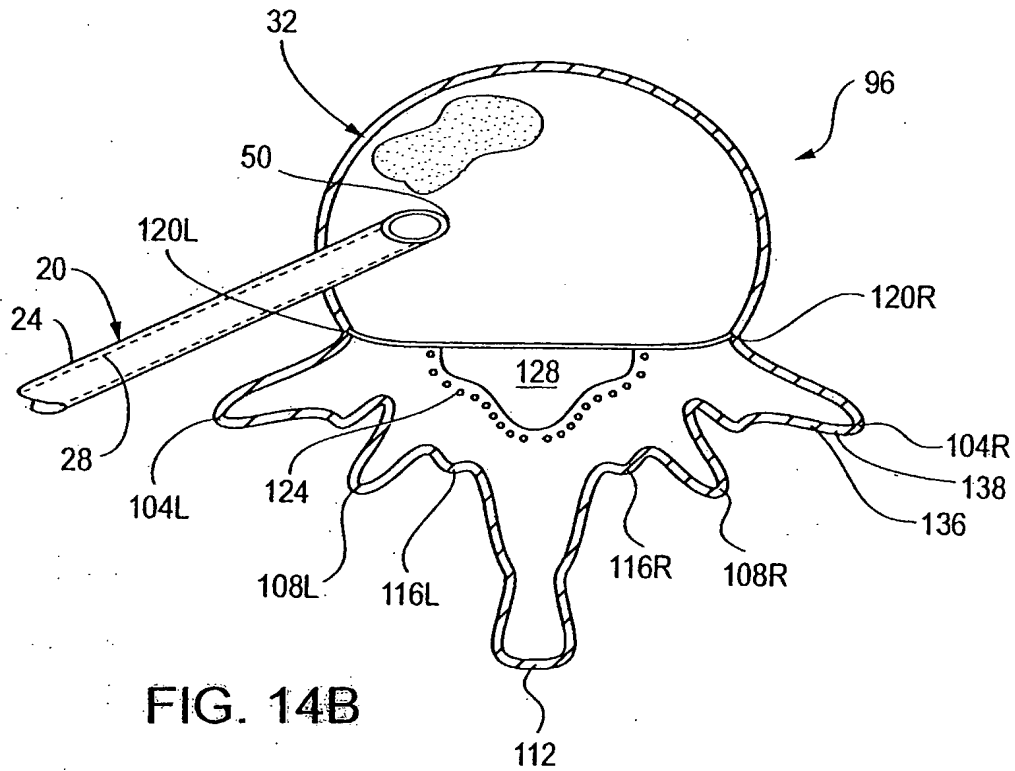
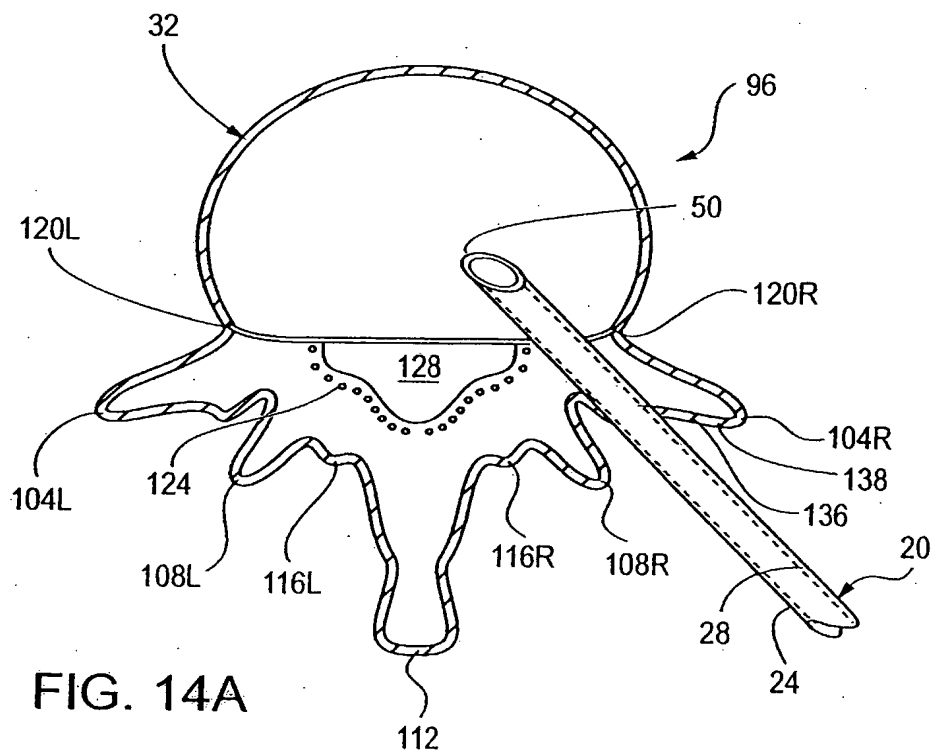
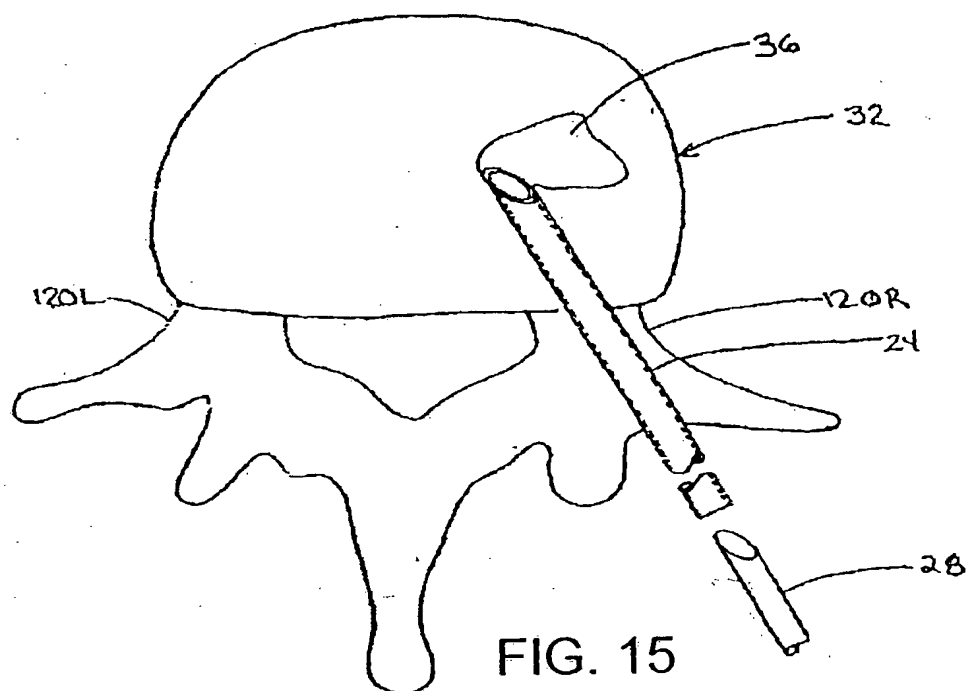


FIG. 12









INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/031605

A. CLASSIFICATION OF SUBJECT MATTER

A61B17/88 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/018292 A1 (KUSLICH STEPHEN D ET AL) 23 January 2003 (2003-01-23) page 1, paragraph 3-12 page 2, paragraphs 19,34 page 3, paragraph 43-45 figures 2,7,8	1,3,7-9
Y	-----	12-14
X	US 6 149 655 A (CONSTANTZ ET AL) 21 November 2000 (2000-11-21) column 1, line 60 - column 2, line 22 column 9, line 46 - column 10, line 19 column 22, line 43 - column 27, line 64 figures 5,29-34	1,3,9,14
A	----- -/--	11

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

3 January 2006

Date of mailing of the international search report

13/01/2006

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Authorized officer

Kakoullis, M

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US2005/031605

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 03/094805 A (SCIMED LIFE SYSTEMS, INC) 20 November 2003 (2003-11-20) page 1, line 5 - page 2, line 19 page 3, line 14 - page 4, line 29 page 12, lines 12-23 page 13, line 6 - page 14, line 28 figure 4A	12, 14
A	-----	1, 3
Y	EP 1 212 993 A (STRYKER TRAUMA GMBH) 12 June 2002 (2002-06-12) column 1, paragraphs 7, 8 figure 2	13
A	-----	1
P, X	WO 2005/025450 A (SKELETAL KINETICS, LLC; CONSTANTZ, BRENT R; DELANEY, DAVID; YETKINLER,) 24 March 2005 (2005-03-24) page 1, line 10 - page 3, line 8 page 5, line 21 - page 6, line 30 page 8, line 28 - page 9, line 11 page 22, line 24 - page 23, line 12 page 24, line 3 - page 28, line 30 figures 1-3, 5A -----	1, 3-9, 12, 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/031605

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15-21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/031605

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			US 2002087164 A1	04-07-2002
WO 2005025450	A	24-03-2005	NONE	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2005/031605

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A cement delivery needle apparatus (20) and a method of flowing a bone cement through a vertebroplasty needle apparatus are provided. The cement delivery needle apparatus (20) includes a sheath (24) and a handle (26). The sheath (24) has an inlet (44) to receive a bone cement and an outlet (40) for expressing the cement into a vertebral body. The handle (26) extends from the sheath (24) and includes a vibration assembly (70) for agitating the cement. The method includes providing a bone cement source to the needle. The method further includes providing a vibration assembly associated with a handle of the needle, agitating the cement with the vibration assembly and injecting the cement through the sheath.